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The effect of orlistat on body weight in obese Czech adults

Research Article

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Abstract: Objectives. The effectiveness of pharmacologic support with orlistat is shown on a group of the obese patients. Methods. In ambulatory patients, basic anthropometric parameters as body weight, BMI, waist circumference and the total amount of adipose tissue were compared before substitution with 120 mg orlistat three times a day and after a four-month therapy. This group included 52 patients who were administered the same dose of orlistat for the whole period of time. The control group consisted of 49 patients. These patients were not administered orlistat. Results. After a four-month therapy with orlistat there was a mean reduction in weight by 6.7 ± 2.6 kg in the monitored group of patients. Their BMI was reduced by 2.0 ± 0.9 kg/m² and the waist circumference by 3.7 ± 3.3 cm. The decrease in the percentage of the total body lipid was 2.5 %. There was a statistically significant reduction in all of the monitored parameters. In the control group, there was no statistically significant decrease in the majority of the monitored parameters. Conclusion. We can state that in our patients we have proven a positive effect of orlistat substitution on their weight reduction.

Keywords: Orlistat • Obesity • Pharmacotherapy of obesity • Weight reduction

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1. Introduction

Obesity is a serious, multifactorial, chronic disease that has reached epidemic proportions in most industrialized countries and is threatening to become a global epidemic as a result of constantly increasing energy intake without an adequate increase in energy expenditure.

Obesity has become the most frequent metabolic disease as a result of life conditions and lifestyle changes which have resulted in a positive energetic balance [1]. The rapidly rising prevalence of obesity is alarming. As far as the number of obese people is concerned the Czech Republic is one of the leading European Union countries both in the obesity of men and of women [2].

The treatment of obesity is based on the consistent observance of diet and exercise regimens. Without this consistent observance pharmacotherapy should not be initiated [3,4]. However, these basic rules are not accepted by the non-professional public as sufficiently effective. A large number of the Czech population lives a sedentary lifestyle with completely insufficient physical activity. This together with dietary mistakes leads to the increase in their body weight. At present there is only a very limited number of drugs in the market which are suitable, effective and safe for the treatment of obesity. Moreover, the European Drug Agency suspended the decision on the registration of sibutramine in the whole of Europe based on the outcomes of SCOUT study (Sibutramine Cardiovascular Outcomes) in January 2010 [5,6]. For this reason an anti-obesity drug containing orlistat is the only standard anti-obesity drug in the Czech market [7,8]. The aim of modern pharmacotherapy of obesity is to help the patients to reduce their weight and to maintain it on a long-term basis or

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to treat the metabolic disorders which predispose the individual to develop obesity [9-11]. The aim of our study was to show how beneficial orlistat is for the out-patient treatment of obesity and at the same time to emphasize that the pharmacotherapy of obesity is an integral part of complex therapy of this severe disease.

2. Methods

All patients diagnosed with and treated for obesity at the Metabolic Clinic of the University Hospital in Hradec Králové are advised to follow a hypocaloric nutritionally balanced diet with an energy content of 5000 – 6000 kJ (kilojoule) for women and 6000-7000 kJ for men during their first visit to the outpatient clinic. At the same time their intake of animal fat is reduced. Long-term physical activity which would involve large muscle groups such as walking, bicycle riding, swimming, cross-country sking etc. last for at least 30 minutes and be carried out for a minimum 3-5 times per week is also recommended.

Of these patients, a group of patients indicated for pharmacotherapy with orlistat at a dose of 120 mg three times a day was selected. This group included 52 patients who were administered the same dose of orlistat for a period of four months. This group consisted of 21 men and 31 women. The average age of patients was 47 years. Their age ranged from 21 to 71 years. The control group consisted of 49 obese patients (28 women and 21 men). As described in current guidelines these patients were in the first phase of weight reduction without pharmacotherapy with orlistat. They were also recommended to observe the same diet and exercise regimen as the orlistat group. The average age of these patients was 46 years. Their age ranged from 22 to 61 years. These patients were not administered orlistat and at the same time were recommended to consistently observe the recommended diet and to increase their regular physical activity.

In all of the obese outpatient patients indicated for pharmacotherapy, the basic anthropometric parameters such as their weight, BMI (body mass index), waist circumference and the total amount of adipose tissue before administration of 120 mg of orlistat three times a day and after a four-month therapy with the same amount of effective substance were compared in the course of the year 2012.

The height of patients was measured on a calibrated height gauge and their weight checked by a calibrated scale. BMI was calculated in a standard way. BMI= weight/height^{2.} Waist circumference was measured using measuring tape. The amount of the total body lipid was measured by a multi-frequency analyzer InBody

720. The InBody made by Biospace company is the first body composition analysis device in the world that uses the 8-point tactile electrode method. This is a multi-frequency analyser which is able to perform a quality analysis of the body composition and which combines bimanual and bipedal measurements. The measurements were carried out on an out-patient basis in the Metabolic Clinic of the University Hospital in Hradec Kralove.

3. Results

After four months of therapy with orlistat at a dose of 120 mg three times a day, there was a mean reduction in weight by 6.7 ± 2.6 kg in the monitored group of patients. BMI was reduced by 2.0 ± 0.9 kg/ height² and the waist circumference was reduced by 3.7 ± 3.3 cm. The decrease in the percentage of the total body lipid was 2.5 %. There was a statistically significant reduction in all of the monitored parameters (Table 1). The initial mean BMI value was 38.2 ± 4.9 kg/height² in the orlistat group. By reducing lipid intake in the diet of the orlistat group, the temporary side-effects of the medication (steatorrhoea, flatulence) disappeared. In the control group there was a mean reduction in the body weight by 0.6 kg. In this group of patients, BMI was reduced by 0.1 ± 0.4 kg/height² and the waist circumference was reduced by 0.5 ± 1.2 cm (Table 2). The decrease in the percentage of the total body lipid was 0.2 ± 0.6 %. In the control group, there was no statistically significant decrease in any of the monitored parameters.

4. Discussion

The orlistat group of patients and the control group are an example of a different approach of a Czech patient to the treatment of obesity. With the current lifestyle of most of the Czech population, the recommendation to reduce the food intake and increase the regular physical activity is not sufficient in obese patients. At present information on suitable weight reduction procedures is easily available in the media. In particular the female part of obese population is successful at the initial stages of their attempts to lose weight by testing various types of the so called "reliable" diets. However, all the obese patients seem to lack the desire and willingness to carry out a regular, long-term and suitable physical activity although without this activity it is not possible for any person to maintain reduced weight. An obese Czech person will prefer suffering from hunger to walking, swimming and bicycle riding.

change

Table 1. Changes in anthropometric parameters, the orlistat group (n = 52)

mean Range Body weight (kg) baseline 117.3 8.8 98.0: 135.0 110.6** month 4 9.0 92.0; 127.0 -6.7° -14.0; 1.8 change 2.6 BMI (kg/m²) baseline 38.2 4.9 31.0; 48.0 36.3** 28 0: 46 0 month 4 49 change -2.0° 0.9 -4.4; -0.4 Waist (cm) baseline 118.7 7.8 108.0; 135.0 115.0** 8.9 98.0: 133.0 month 4 change -3.7° 3.3 -15.0; 0 Body fat (%) 36.6 baseline 5.5 24.8: 49.8 34.1** month 4 5 4 23.9: 48.5 change -2.5° -4.6; 0 1.1 Body fat (kg) 17.2; 64.2 baseline 44.9 8.3 39 7** 8.0 15.7:62.8 month 4

** Significantly different from baseline, P < 0,001 (pair Student's t-test)

Significantly different from the control group,
P < 0,001 (pair Student's t-test)

-8.7: 0

Moreover, most of the obese Czech patients think that if the doctor does not prescribe them medication, the treatment is not sufficient. Besides the effects of medication, patient's motivation is also important. After four months of treatment with orlistat, there was a statistically significant reduction in all the monitored parameters. The control group consisted of patients who attended the weight reduction advisory centre for the first time and began conservative therapy without taking anti-obesity drugs as described in the current guidelines. Based on the results of this control group, it is obvious that most of these patients will need pharmacotherapy or surgical intervention in the future. Because the orlistat patients paid for the medication themselves their motivation to reduce weight increased. The control group of patients lacked such a motivation because no medication was prescribed to them. They were only

Table 2. Changes in anthropometric parameters, the control group (n = 49)

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	mean	SD	range
Body weight (kg)			
baseline	107.2	9.5	90.0; 125.0
month 4	106.7*	9.6	88.4; 125.0
change	-0.6	1.4	-2.8; 3
BMI (kg/m²)			
baseline	35.3	3.5	30.0; 44.0
month 4	35.2	3.6	29.6; 44.0
change	-0.1	0.4	-0.8; 0.9
Waist (cm)			
baseline	109.0	7.6	91.0; 129.0
month 4	108.6*	7.7	89.0; 129.0
change	-0.5	1.2	-2.0; 2.0
Body fat (%)			
baseline	34.1	4.6	24.2; 44.3
month 4	33.9	4.5	24.0; 44.8
change	-0.2	0.6	-1.0; 1.2
Body fat (kg)			
baseline	36.6	6.5	21.8; 51.0
month 4	36.2	6.4	21.2; 49.9
change	-0.4	1.0	-1.9; 2.3

^{*} Significantly different from baseline, P < 0,05 (pair Student's t-test)

recommended to increase their physical activity and prohibited to eat the food they like or recommended to reduce its amount. Most of the patients treated in this way consider this treatment to be insufficient. Sooner or later they require prescription of medication. However, no miracle pills exist. Medication containing or listat helps to reduce body weight, however if the patients do not observe other recommendations, its therapeutic effect reduces [12,13].

The constant increase in the number of obese patients requires a complex therapy of obesity within the preventive programmes and in everyday medical practice. Only a complex approach to obese patients and the utilization of all available therapeutic methods provides a chance for success. Weight reduction has a positive influence on the quality of life and can significantly decrease health risks of all the obese patients.

The treatment with orlistat is not financially demanding for the health-care system because this treatment is paid by the patients themselves [14,15].

The current affordability of orlistat-containing preparations in the Czech market allows a great number of obese patients to take this medication.

In addition to orlistat, other substances, which are primarily designated for other indications, are also available, however they have a different amount of side anti-obesity effect.

Exenatide and liraglutide are glucagon-like peptide-1 agonists, medication of which is primarily approved for the treatment of diabetes mellitus type 2 [16,17]. However, exenatide has a subtle prolonged effect on reduction of appetite and most people using exenatide are slowly losing weight. Liraglutide also decreases appetite and maintains body weight and lowers blood triglyceride levels. A relative disadvantage of glucagon-like peptide-1 agonists is that it is administered by subcutaneous injection.

<u>Phentermine</u> is a psychostimulant of the phenethylamine class. Phentermine is used for the short-term treatment of obesity as an appetite suppressant. The drug may increase blood pressure and heart rate. It may also cause palpitations, restlessness, and insomnia. Additionally, phentermine has the potential to cause psychological dependence. On the other hand, combination of phentermine/topiramate reduces a food intake and potentially achieves greater improvements in weight and cardiovascular risk reduction than a monotherapeutic weight loss agent [18,19].

The combination of <u>naltrexone/bupropion</u> can also be well tolerated and lead to clinically meaningful weight

loss with improvements in cardiometabolic risk markers, weight related quality of life and eating control. Naltrexone, a pure opioid antagonist, is a synthetic relative of oxymorphone and naloxone. Bupropion, an antidepressant of the amino-ketone class, is a dopamine reuptake inhibitor. The mechanism by which the combination of naltrexone/bupropion induces weight loss is not entirely understood [20]. The effects of naltrexone/bupropion may be beneficial in the long-term treatment of adult obesity, but further investigation of the drug's safety profile is required. We can only hope that other anti-obesity drugs will appear in the market in the near future and help fight this chronic disease.

5. Conclusion

We can state that in our patients we have proven a positive effect of orlistat on their weight reduction. An anti-obesity agent containing orlistat is a modern drug for long-term, safe and effective weight reduction under the condition that the diet and the exercise regimen are observed. Besides dietary recommendations, behavioural techniques and increased regular physical activity, pharmacotherapy of obesity is an integral part of the complex therapy of this disease. Surgical intervention can be considered only if all the above-mentioned therapeutic procedures have not been successful.

Conflict of interest

None

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